swissethics Newsletter

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Information on the coronavirus

March 18, 2020

Sponsors, investigators and project leaders of clinical trials and research projects in Switzerland must ensure that the studies are conducted in line with the COVID-19 Ordinance 2 (available in German (PDF), French (PDF) and Italian (PDF), issued by the federal government on 16 March 2020.

In particular, participants over the age of 65 and participants with underlying medical conditions must follow the instructions issued by the federal government in any circumstances. The instructions are published on the FOPH webpage (in German, in French, in Italian, in English).

Adapting to the situation: general remark

The coronavirus has a serious impact on the conduct of studies in Switzerland. It is the responsibility of the investigator and the sponsor to guarantee participants safety. Rescheduling visits or interrupting aggressive therapies and thus avoiding unnecessary risks must always be considered, especially for older patients, those with pre-existing conditions and in a high-risk group for the COVID-19.

If studies have to be interrupted, the sponsors, investigators and the project leaders should follow the following procedure.

Clinical trials according to ClinO

If the sponsor decides to temporarily interrupt or definitively discontinue a clinical trial, this shall be notified to the ethics committee within 15 days, as per ClinO art 38 abs 2.

A temporary interruption of the recruitment in an active ongoing clinical trial, **must not be notified** to the ethics committee, but documented in the central and site study file.

The applicants of multiple clinical trials (sponsors, institutions, hospitals, CROs, etc.) should notify the interruptions and discontinuations of the clinical trials concerned, in a single notification. This means by submitting a list indicating all concerned projects. It is recommended to contact the Lead ethics committee before doing so.

Amendments to the trial protocol and or changes of the rights and obligations of the participants, have to be submitted and approved by the ethics committee prior to their implementation.

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Protocol deviations (like skipping patient visits), which could occur now, do not need to be reported to the ethics committees but documented as per GCP (see guidance on protocol deviations).

If, because of the temporarily interruption, the clinical trial duration is extended beyond the trial end date originally notified to the ethics committee, the trial extension must be notified to the ethics committee when the clinical trial resumes.

Research projects with persons, according to HRO Chapter 2

If the sponsor or project leader decides to temporarily interrupt the research project or the recruitment in an active ongoing research project due to the coronavirus, a notification to the ethics committee is not necessary.

Such temporary interruption must be documented in the study file.

Amendments to the trial protocol and or changes of the rights and obligations of the participants, have to be submitted and approved by the ethics committee prior to their implementation.

If, because of the temporarily interruption, the research project duration is extended beyond the project end date originally notified to the ethics committee, the project extension must be notified to the ethics committee when the research project resumes.

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March 16, 2020

The corona virus also does not stop at the ethics commissions. Not all the scheduled committee meetings can be held regularly at the various locations. This means that there may be delays in the decision-making process and therefore deadlines cannot always be met. The ethics committees thank you for your understanding.

Nevertheless, the reviews and approvals of studies investigating the disease or investigational medicinal products for Covid-19 are of course treated with priority.

We thank you for your cooperation in this critical situation. In individual cases, the ethics committees are available to answer questions on this matter directly

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